

§ 870.1

870.4370 Roller-type cardiopulmonary bypass blood pump.
870.4380 Cardiopulmonary bypass pump speed control.
870.4390 Cardiopulmonary bypass pump tubing.
870.4400 Cardiopulmonary bypass blood reservoir.
870.4410 Cardiopulmonary bypass in-line blood gas sensor.
870.4420 Cardiopulmonary bypass cardiotomy return sucker.
870.4430 Cardiopulmonary bypass intracardiac suction control.
870.4450 Vascular clamp.
870.4475 Surgical vessel dilator.
870.4500 Cardiovascular surgical instruments.
870.4875 Intraluminal artery stripper.
870.4885 External vein stripper.

Subpart F—Cardiovascular Therapeutic Devices

870.5050 Patient care suction apparatus.
870.5100 Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheter.
870.5150 Embolectomy catheter.
870.5175 Septostomy catheter.
870.5200 External cardiac compressor.
870.5225 External counter-pulsating device.
870.5300 DC-defibrillator (including paddles).
870.5310 Automated external defibrillator.
870.5325 Defibrillator tester.
870.5550 External transcutaneous cardiac pacemaker (noninvasive).
870.5800 Compressible limb sleeve.
870.5900 Thermal regulating system.
870.5925 Automatic rotating tourniquet.

AUTHORITY: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

SOURCE: 45 FR 7907-7971, Feb. 5, 1980, unless otherwise noted.

EDITORIAL NOTE: Nomenclature changes to part 870 appear at 73 FR 35341, June 23, 2008.

Subpart A—General Provisions

§ 870.1 Scope.

(a) This part sets forth the classification of cardiovascular devices intended for human use that are in commercial distribution.

(b) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under part 807 may not show merely that the device is accurately described by the section title and identification provisions of a regulation in

21 CFR Ch. I (4–1–11 Edition)

this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

(c) To avoid duplicative listings, a cardiovascular device that has two or more types of uses (e.g., used both as a diagnostic device and as a therapeutic device) is listed only in one subpart.

(d) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

[52 FR 17735, May 11, 1987, as amended at 68 FR 61344, Oct. 28, 2003]

§ 870.3 Effective dates of requirement for premarket approval.

A device included in this part that is classified into class III (premarket approval) shall not be commercially distributed after the date shown in the regulation classifying the device unless the manufacturer has an approval under section 515 of the act (unless an exemption has been granted under section 520(g)(2) of the act). An approval under section 515 of the act consists of FDA's issuance of an order approving an application for premarket approval (PMA) for the device or declaring completed a product development protocol (PDP) for the device.

(a) Before FDA requires that a device commercially distributed before the enactment date of the amendments, or a device that has been found substantially equivalent to such a device, has an approval under section 515 of the act FDA must promulgate a regulation under section 515(b) of the act requiring such approval, except as provided in paragraph (b) of this section. Such a regulation under section 515(b) of the act shall not be effective during the grace period ending on the 90th day after its promulgation or on the last day of the 30th full calendar month after the regulation that classifies the device into class III is effective, whichever is later. See section 501(f)(2)(B) of the act. Accordingly, unless an effective date of the requirement for premarket approval is shown in the regulation for a device classified into class